UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,358	02/08/2002	Malcolm Clive Carter	PG3416US2	2600

23347 7590 05/27/2003

DAVID J LEVY, CORPORATE INTELLECTUAL PROPERTY
GLAXOSMITHKLINE
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	**PAPER NUMBER**
1624	4

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,358	CARTER ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on (1/21/03) - Prelim Amdt.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/582,746 .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This is a continuation of 09/ 582,746 filed on 6-30-00. The preliminary amendment of 01-21-03 has been entered. Said amendment changes the dependency of claims 4-12, and add new claims 13-36. The compound in claim 13 has support on line 13, page 34. The compound in claim 25 has support on line 27, page 37. The treatments of various diseases are mentioned on page 1.

Claims 1-36 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 3, 5, 6, 8, 10-12, 15, 17, 18, 20, 22-24, 27, 29, 30, 32, and 34-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast, gastric, head & neck tumors, does not reasonably provide enablement for the treatment of various cancers (e.g., ovarian, pancreatic, non-small cell lung, bladder), psoriasis, and rheumatoid arthritis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling

disclosure:

(1) The quantity of experimentation necessary;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The breadth of the claims;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

On page 108, the specification provides a cellular assay for breast, head & neck, and gastric tumor cell lines. The result of said assay is listed in Table 2 on page 109. Said assay does not indicate whether the tumor cells are benign or malignant. Thus, at best, the efficacy can only be applied to solid benign tumors, and cannot be extrapolated to cancers since malignancy is associated with cancers. For a compound to be able to inhibit one type of cell growth, it does not mean said compound can inhibit all types of cell growth. The state of the art has not had a compound that can treat pancreatic cancer. Regarding breast and ovarian cancers, they are treated by surgery, which is followed by a therapy of ER (estrogen receptor) antagonist. Similarly, non-small cell lung and bladder cancer are treated by surgery. Once any cancer is metastasized, there is virtually no effective therapy.

Because different types of cancers affect different organs and have different modes of growth and harm to the body as well as different vulnerabilities, the existence of such a "silver

bullet" is contrary to our present understanding in oncology. Therefore, it is beyond the skill of oncologists today to get an agent to be effective against many cancers, tumor growth claimed herein.

Regarding psoriasis, and rheumatoid arthritis, their etiologies are not linked to cell growth. Thus, it cannot be perceived how the claimed compounds can treat said diseases. Currently, psoriasis is treated with topical lubricants, keratolytics, methotrexate and corticosteroids while rheumatoid arthritis is treated with NSAID's, anti-leukotriene, COX-2 inhibitors, and corticosteroids. Except methotrexate, no other chemotherapeutic agent is known to treat psoriasis, or rheumatoid arthritis. Thus, one skilled in the art will have to carry out undue experimentation to establish a pharmacological profile for each of the claimed compounds in the treatment of psoriasis, and rheumatoid arthritis.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, ***In re Ferens***, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal requires undue experimentation, ***Genetech vs. Novo Nordisk***, 42 USPQ 2nd 1001, 1006.

2. **Lack of Description:** Claims 7, 19, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Said claims recite "a method...wherein the cancer is a susceptible stomach cancer", which has no description in the specification. What is described in

the specification is "gastric cancer", which is specific to an organ. The phrase "stomach cancer" also suggests cancer or tumor in the abdominal region, or any organ within the abdominal cavity (liver included). Therefore, the scope of "stomach cancer" has no written description.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 2, 10-14, and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 8, 10, 12, 16, 24, 25, 28, 29, 31, and 32 of U.S. Patent No. 6,391,874. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions, and compounds of formula (I) are embraced by those in US'874, particularly when formula (I) in US'874 has the following substituents:

a. X is N, and Y is W, which can be $-NR^a$, with R^a as hydrogen;

b. R^1 is furanyl substituted with R^3; R^2 is hydrogen;

c. R^3 is M^1-M^2-M^3-M^4, which is a 'methylsulphonylethylaminomethyl';

d. U is phenyl substituted with R^6 as ZR^7, and optionally substituted with R^4 as halogen;

e. Z is –O-, and R^7 is a carbocyclic ring.

Claim 1 of US'874 differs from the instant claim 52 by covering a larger genus. However, such a difference constitutes a difference in scope. It is still obvious that the compositions and compounds claimed herein fall within the scope of those claimed in US'874.

4. Claims 1-36 are **provisionally** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52, 53, 56, and 58-59 of copending application 09/ 582,746. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method claimed herein are embraced by those claimed in copending application No. 09/ 582,746. Note, compounds of claims 1, 13, and 25 in the instant application are embraced by the formula (I) of the copending application with the following substituents:

a. Ar is furan or thiazole;

b. R^2 is hydrogen;

c. R^4 is chloro or bromo.

The first compound recited in claim 68 of the copending application is the same compound recited in claim 1 of the instant application. The second compound recited in claim 68 of the copending application is the same compound recited in claim 25 of the instant

application. The third compound recited in claim 68 of the copending application is the same compound recited in claim 13 of the instant application. The same pharmaceutical compositions and methods of treatment are claimed in both instances.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Tamthom N. Truong
Examiner
Art Unit 1624

***

May 23, 2003